

INSERTION SYSTEM FOR INTRAOCULAR LENS

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates to a system for inserting a deformable intraocular lens into the eye. Examples of such a deformable intraocular lens include a deformable intraocular lens that is inserted into the eye in place of the natural lens when the latter is physically extracted because of cataracts, and a vision correction lens that is inserted into the eye for the sole purpose of vision correction.

Description of the Related Art:

In general, during cataract surgery, an intraocular lens is inserted into the eye, from which the natural lens has been removed (lens-removed eye), such that the intraocular lens is located in the original position previously occupied by the natural lens and restores vision. Various studies on the material and shape of such an intraocular lens have been carried out since Ridley performed the first implantation of an artificial lens in 1949.

In recent years, in addition to studies on intraocular lenses which are used for vision restoration after cataract surgery, intense studies on intraocular lenses for refractivity correction have been ongoing. Such an intraocular lens for refractivity correction is inserted into the eye which still has a natural lens (lens-carrying eye),

for correction of nearsightedness or farsightedness.

In relation to cataract surgery, a technique for crushing the lens tissue by means of ultrasonic emulsification and suctioning the crushed tissue away has been popularized. This technique enables performance of lens removal surgery to excise an opaque lens through a small incision. Along with progress in the operational technique itself, intraocular lenses themselves have recently been improved. Such an improved intraocular lens is disclosed in, for example, Japanese Patent Application Laid-Open (kokai) No. 58-146346. In the intraocular lens, the optical portion is made of a deformable elastic material. The intraocular lens is inserted, in a folded state, into the eye through a small incision and restored to its original shape within the eye allowing it to exert its proper lens function.

Accompanying these technical developments, the material of the optical portion of such an intraocular lens has been changed gradually from hard polymethyl methacrylate (PMMA) to silicone or soft acrylic resin, which enables the intraocular lens to be inserted into the eye in a folded state.

Moreover, in recent years, studies have been conducted on copolymers such as hydroxyethyl methacrylate and methyl methacrylate, as well as on hydrophilic materials such as 2-hydroxyethyl methacrylate (HEMA).

Further, intraocular lenses of different shapes have been studied and put into practical use, including an intraocular lens having a circular optical portion and loop-

shaped support portions formed of different materials, an intraocular lens whose loop-shaped support portions and optical portion are formed of the same material, and an intraocular lens having plate-shaped support portions.

Furthermore, the following patent publications disclose insertion devices for inserting the above-described deformable intraocular lens into the eye in a compressed or folded state.

(1) Japanese Patent Application Laid-Open (*kokai*) No. 5-103803 discloses a device designed such that a holding member which holds a folded lens is attached to a main body, and the lens is inserted into the eye through an insertion tube provided at the tip end of the holding member.

(2) Japanese Patent Application Laid-Open (kokai) No. 7-23991 discloses a disposable insertion device for one-time use in which a portion for holding a folded lens is integrated with a main body of the device and the entirety of the device is formed of resin.

(3) Japanese *Kohyo* (PCT) Patent Publication No. 9-506285 discloses an intraocular-lens insertion device having a broadened range of applications. In the intraocular-lens insertion device, a lens is held in a stress-free state in an intermediate preparation region of a main body. After attachment of a cannulae (insertion tube) to the main body, the intraocular lens is inserted into the eye through the cannulae. The intermediate region serves as a lens package.

The conventional intraocular-lens insertion devices

described in (1) and (2) above have the following drawbacks. When either of these devices is used, an intraocular lens removed from a package is placed on a placement portion of the device, is deformed, and then inserted into the eye. Therefore, during actual operation, work for placing the intraocular lens onto the device is needed, resulting in increased time and labor involved in implantation of the intraocular lens.

Further, such an intraocular lens and insertion device must be made germ-free through a sterilization procedure, because they are inserted into the eye through an incision. However, if an operator accidentally drops the lens and/or the insertion device onto an unclean surface, such as a floor or table, during the placement operation, the germ-free state is lost, and the lens and/or the insertion device becomes unusable.

Further, when the operator forcedly inserts into the eye an intraocular lens which has been placed on the device improperly, the lens may be broken, or may forcibly fly out from the insertion tube, potentially resulting in damage to the internal tissue of the eye.

The intraocular-lens insertion device described in (3) above has the following drawbacks. Although the intermediate region of the device can be used as a lens package, work for attaching a cannulae (insertion tube) to the main body must be performed during actual use, because the cannulae (insertion tube) is a member which is formed separately from

09745123-122000

the main body. Although a technique for storing in advance an intraocular lens at the intermediate region located on the center axis of a push rod, the intermediate region is difficult to be formed from a material suitable for storing the lens. In addition, the intermediate region cannot be formed to have a function necessary for properly holding an intraocular lens having loop-shaped support portions. That is, although such an intraocular lens must be stored in a state in which the angle between the optical portion and the support portions of the intraocular lens is maintained, the intermediate region of the conventional insertion device cannot provide such an angle maintaining function.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an insertion system for a deformable intraocular lens, which system eliminates or simplifies an operation of placing a lens on an insertion device to thereby save the time involved in the placement operation, while solving drawbacks involved in conventional insertion devices, such as breakage of a lens or improper insertion of a lens, which would otherwise be caused by an improper operation by an operator.

Another object of the present invention is to provide an insertion system for a deformable intraocular lens, which system enables an operator to freely select an intraocular lens and an insertion device in consideration of a selected operation method or the status of a patient.

00022T 02T5460

In order to achieve the above objects, the present invention provides an insertion system for an intraocular lens, comprising: an intraocular lens having a deformable optical portion; a lens package for storing the lens in a state in which no stress acts on the optical portion of the lens; deforming means for deforming the lens to a reduced size; and an insertion device having, an insertion tube through which the deformed lens is inserted into an eye, and a pusher mechanism for pushing and inserting the lens into the eye. The lens package has a function for attachment to the insertion device and a function for acting as a portion of the mechanism to be provided by the insertion device.

The insertion system according to the present invention eliminates or simplifies an operation of removing an intraocular lens from a lens case and setting a lens on an insertion device. In addition, the insertion system according to the present invention prevents erroneous operation, to thereby improve safety. Further, the insertion system enables an operator to freely select an intraocular lens and an insertion device to thereby obtain an intraocular-lens insertion system optimal for a selected operation method or the status of a patient.

Preferably, the deforming means is formed integrally with the insertion tube. In this case, the structure of the insertion device for deforming the intraocular lens can be simplified.

Preferably, at least a portion of the deforming means

is formed integrally with the lens package. In this case as well, the structure of the insertion device for deforming the intraocular lens can be simplified.

Preferably, when the lens package is attached to the insertion device, the center of the lens coincides with the center axis of a push rod which constitutes the pusher mechanism. This structure enables the intraocular lens to be automatically positioned at a position for use, through an operation of attaching the lens package to the insertion device.

Preferably, the insertion system further comprises a lens moving mechanism for moving the lens from a standby position at which the center of the lens does not coincide with the center axis of a push rod which constitutes the pusher mechanism to an insertion position at which the center of the lens coincides with the center axis of the push rod. This structure enables the lens package to have an additional function other than the function of storing the lens. An example of such an additional function is maintaining an angle between the support portions and the optical portion of the lens. In addition, through a simple operation of moving the lens, the intraocular-lens insertion system can be brought into a state for use.

BRIEF DESCRIPTION OF THE DRAWINGS

Various other objects, features and many of the attendant advantages of the present invention will be readily

appreciated as the same becomes better understood by reference to the following detailed description of the preferred embodiment when considered in connection with the accompanying drawings, in which:

FIG. 1 is a perspective view showing the concept of an intraocular-lens insertion system according to the present invention;

FIGS. 2A and 2B are views showing a first embodiment of the intraocular-lens insertion system according to the present invention, wherein FIG. 2A is a front view of an insertion device carrying a lens case, and FIG. 2B is a bottom view of the insertion device;

FIGS. 3A to 3D are views showing the lens case shown in FIG. 2A, wherein FIG. 3A is a plan view of the lens case, FIG. 3B is a left side view of the lens case, FIG. 3C is a right side view of the lens case, and FIG. 3D is a cross section taken along line 3D-3D in FIG. 3A;

FIG. 4 is a front view corresponding to FIG. 2A and showing a state in which the lens case is separated from the insertion device;

FIG. 5 is a view showing a modification of the first embodiment shown in FIGS. 2A and 2B;

FIG. 6 is a front view showing a modified example of the insertion tube employed in the first embodiment;

FIGS. 7A and 7B are views showing a second embodiment of the intraocular-lens insertion system according to the present invention, wherein FIG. 7A is a front view of an

insertion device showing a state in which the lens case has been attached to the insertion device and in which the intraocular lens is located at a first or standby position, and FIG. 7B is a front view of the insertion device showing a state in which the lens is located at a second or insertion position;

FIGS. 8A to 8C are views showing a state in which the lens case is separated from the insertion device shown in FIGS. 7A and 7B, wherein FIG. 8A is a front view of the insertion device, FIG. 8B is an enlarged plane view of the lens case, and FIG. 8C is a cross section taken along line 8C-8C in FIG. 8B;

FIGS. 10A and 10B are views showing the second embodiment, wherein FIG. 10A is a cross section taken along line 10A-10A in FIG. 7A, and FIG. 10B is a cross section taken along line 10B-10B in FIG. 7B;

FIG. 12 shows cross sections corresponding to those of FIGS. 10A and 10B and showing another modification of the

second embodiment shown in FIGS. 7A and 7B, in which the lens case has a modified base portion; and

FIG. 13 is a plan view showing a modified example of the insertion tube of the insertion device used in the second embodiment.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Embodiments of the present invention will be described with reference to the accompanying drawings.

FIG. 1 is a perspective view showing the concept of an intraocular-lens insertion system according to the present invention.

The system according to the present invention is mainly composed of a lens case 10, which serves as a lens package for storing an intraocular lens 20, and an insertion device 30 for inserting the intraocular lens 20 into the eye of a patient.

The lens case 10 includes a lens case top 11 and a lens case bottom 12, which are assembled so as to form a space 15 for storing the intraocular lens 20. The lens case 10 has a through hole 13, which penetrates the lens case 10 in the longitudinal direction thereof and which serves as a portion of the mechanism to be provided by the insertion device 30. An insertion tube 32 is formed at the tip end of the insertion device 30 via an attachment portion 35. The intraocular lens 20 is inserted into the eye of the patient through the insertion tube 32. A pusher mechanism 34 is

disposed at the rear end 31a of a tubular main body 31 of the insertion device 30. The pusher mechanism 34 is coupled to the rear end of a push rod 33 for pushing the intraocular lens 20 into the eye.

The lens case 10 is formed to have a size that enables attachment of the lens case 10 to the attachment portion 35 of the insertion device 30. The lens case 10 is fixed onto the attachment portion 35 while being aligned therewith by means of a projection 14 projecting from the lens case top 11 of the lens case 10 and an engagement hole 36 formed in the attachment portion 35. Subsequently, the push rod 33 is advanced by means of the pusher mechanism 34. As a result, the intraocular lens 20 stored in the lens case 10 is pushed out from the tip end 32a of the insertion tube 32 and inserted into the eye.

The above-described structure realizes the concept of the present invention such that when the lens case 10 serving as a lens package is attached to the insertion device 30, the lens case 10 functions as a portion of the mechanism to be provided by the insertion device 30.

FIGS. 2A and 2B are views showing a first embodiment of the intraocular-lens insertion system according to the present invention, wherein FIG. 2A is a front view of the insertion device 30 to which the lens case 10 has been attached, and FIG. 2B is a bottom view of the insertion device 30.

The tubular main body 31 of the insertion device 30 is

formed of transparent or semi-transparent plastic such that the diameter at the base end 31a is smaller than that at the tip end 31b. The above-mentioned push shaft 33 is disposed to be located on the center axis of the tubular main body 31, and the through hole of the tapered insertion tube 32 is aligned with the center axis of the tubular main body 31.

The above-mentioned engagement hole 36 is formed in the horizontal region of the attachment portion 35, and a notch is formed on the rearward-facing surface of a front-side vertical wall of the attachment portion 35. The engagement hole 36 and the notch 37 cooperate to position the lens case 10 relative to the attachment portion 35.

As is clearly shown in FIGS. 3A to 3D, the lens case 10 is constituted through assembly of the lens case top 11, on which is placed the intraocular lens 20, and the lens case bottom 12 formed to cover the upper face of the intraocular lens 20 placed on the lens case top 11.

FIG. 3A is a plan view of the lens case, FIG. 3B is a left side view of the lens case, FIG. 3C is a right side view of the lens case, and FIG. 3D is a cross section taken along line 3D-3D in FIG. 3A;

A groove-shaped depression 11a is formed on the upper surface of the lens case top 11 such that the depression 11a extends in the horizontal direction in FIG. 3A. Support portions 22 of the intraocular lens 20 for supporting the optical portion 21 of the intraocular lens 20 are placed in the depression 11a. The above-described projection 14 to be

engaged with the engagement hole 36 of the attachment portion 35 is formed on the lower surface of the lens case top 11 to be located at a position which is slightly offset rightward from the center in FIG. 3A. The lens case bottom 12 for covering the upper surface of the lens case top 11 is formed such that the lens case bottom 12 can be fitted onto the lens case top 11 while covering the upper surface and circumferential (side) surface of the lens case top 11. The above-described through hole 13 is formed in the left and right walls 12a and 12b such that the center of the through hole 13 is aligned with the center axis of the tubular main body 31 of the insertion device 30 when the lens case 10 is attached to the attachment portion 35.

The specific procedure for placement of the lens case 10 is as follows. First, the intraocular lens 20 is placed on the lens case top 11 such that the optical portion 21 of the lens 20 corresponds to the depression 11a of the lens case top 11 and such that the optical portion 21 and support portions 22 of the intraocular lens 20 are supported by the edge portions of the depression 11a. Subsequently, the lens case bottom 12 is placed on the lens case top 11, so that a space 15 is formed between the lens case bottom 12 and the lens case top 11. The space 15 has a shape and size such that movement of the intraocular lens within the space 15 is restricted. Further, the shape of the space 15 is determined such that the optical portion 21 of the intraocular lens 20 does not come into contact with the inner surface of the lens

case top 11 or the inner surface of the lens case bottom 12, thereby preventing the optical characteristics of the optical portion 21 from changing due to force acting on the optical portion 21 during long-term storage.

The through hole 13 of the lens case 10 is reduced in diameter toward the tip end thereof. The intraocular lens 20 and the push rod 33 pass through the through hole 13. After attachment of the lens case 10 to the insertion device 30, the push rod 33 is advanced through operation of the pusher mechanism 34. As a result, the intraocular lens 20 within the lens case 10 is gradually deformed to a smaller size and is moved into the insertion tube 32. Subsequently, after the tip end 32a of the insertion tube 32 is inserted into the eye through an incision formed thereon, the push rod 33 is advanced further, so that the intraocular lens 20 is deformed to a further reduced size by means of the insertion tube 32 and is then pushed into the eye.

Thus, the lens case 10 provides a portion of the function of the insertion device 30 upon attachment to the insertion device 30.

FIGS. 3B and 3D show the diameter of the through hole 13 of the lens case 10 being gradually reduced toward the tip end thereof. That is, the transverse dimension C of the space 15—which receives the intraocular lens 20 placed on the lens top case 11 of the lens case 10 as shown in FIG. 3D—is reduced to a transverse dimension D which corresponds to that measured at the tip end of the through

attached to the insertion device 30 from above. However, the present invention is not limited to such a style of attachment, and an alternative attachment method may be employed. Specifically, the lens case 10 carrying the intraocular lens 20 is placed on a desk or table in a state in which the projection 14 of the lens case top 11 faces upward; and the insertion device 30 is inverted and placed on the lens case 10 from above so as to cover it.

Since such an intraocular-lens insertion system must be used in a germ-free environment, during actual use of the insertion system, an operator must use the system while wearing gloves, which hinders fine operation. Therefore, the above-described attachment method in which attachment of the lens case 10 is achieved through moving the insertion device 30—which is larger and easier to hold than the lens case 10—is preferable.

FIG. 5 is a view showing a modification of the first embodiment shown in FIGS. 2A and 2B. In place of the engagement hole 36 provided on the attachment portion 35, an engagement groove 38 is provided. The engagement groove 38 extends in a direction perpendicular to the push rod 33. The lens case 10 is attached to the insertion device 30 from the side thereof and is fixed by means of a notch 39. Portions other than the above-mentioned portions are denoted by the same reference numerals as those used in FIG. 2, and their repeated descriptions are omitted.

In the present embodiment as well, the attachment

In the above-described embodiment, the intraocular lens 20 has plate-shaped support portions 22 extending from the opposite ends of the optical portion 21.

In the specification, the term "center of the intraocular lens 20" refers to the center in the thickness direction located on the optical axis of the optical portion 21.

A second embodiment of the intraocular-lens insertion system according to the present invention will now be described with reference to FIGS. 7A to FIG. 13. In the present embodiment, an intraocular lens 50 horizontally stored in a lens case 40 serving as a lens package is moved between a first or standby position at which the vertical position of the center of the intraocular lens 50 does not coincide with the center axis of the push rod 33 of the insertion device 30, and a second or insertion position at which the vertical position of the center of the intraocular lens 50 coincides with the center axis of the push rod 33 of the insertion device 30, so that the intraocular lens 50 can be pushed out by the push rod 33.

FIG. 7A is a front view of the insertion device 30 to which the lens case 40 has been attached and in which the intraocular lens 50 is located at the first or standby position, and FIG. 7B is a front view of the insertion device 30 in which the intraocular lens 50 is located at the second or insertion position.

In the first or standby position shown in FIG. 7A, the

longitudinal directions in order to maintain the angle θ between the optical portion 51 and the support portions 52 of the intraocular lens 50. The lens case top 41 has on its bottom surface 41b inclined surfaces to be mated with the inclined surfaces 42a of the lens case base 42. After placement of the lens 50 on the lens case base 42, the lens case top 41 is placed on the lens case base 42, so that the support portions 52 of the lens 50 are sandwiched between the lens case base 42 and the lens case top 41.

As described above, the lens case top 41 is provided with the push member 43. As shown in FIGS. 9A and 9B, the lens case base 42 has an opening 42c in the top surface thereof and projections 42e in the vicinity of the lower ends of opposite side walls 42d. The projections 42e elastically engage with engagement steps 38 formed in the vicinity of the lower ends of the lateral side surfaces of the attachment portion 35. The longitudinal opposite ends of the lens case base 42 are opened, giving the lens case base 42 a squarish C-like cross section. Further, the paired engagement portions 42b are formed on the inner surfaces of the side walls 42d to be located at the approximate center in the vertical direction. The engagement portions 42b extend in the longitudinal direction and are adapted to receive the peripheral portions of the optical portion 51 and the support portions 52 of the intraocular lens 50. As shown in FIG. 8C, the inclined surfaces 42a each having an inclination angle θ are formed on the engagement portions 42b in order to

maintain the angle θ between the optical portion 51 and the support portions 52 of the intraocular lens 50.

The lens case top 41 to be inserted into the top surface opening 42c of the lens case base 42 has a hollow nipping member 41a having a rectangular frame-like shape, and the above-mentioned push member 43 is disposed in the nipping member 41a to be movable in the vertical direction. The bottom surface 41b of the nipping member 41a has inclined portions to come into contact with the inclined surfaces 42a of the engagement portions 42b of the lens case base 42. Upper and lower depressions 41d and 41e are formed at a predetermined interval on each of the inner surfaces 41c of the opposite lateral walls such that the upper depressions 41d are opposed to each other and the lower depressions 41e are opposed to each other.

The above-mentioned push member 43 is inserted into the opening 41f of the nipping member 41a and is pressed downward in order to move the intraocular lens 50 from the standby position to the insertion position. The push member 43 has a head portion 43a of large diameter and a prism-shaped leg portion 43b. Protrusions 43c are formed on the peripheral surface thereof and in the vicinity of the lower end thereof so as to be engaged selectively with the upper depressions 41d or the lower depressions 41e of the nipping member 41a. Specifically, at the standby position, the protrusions 43c of the push member 43 engage the depressions 41d, and when the push member 43 is pressed, the protrusions 43c move downward

and come into engagement with the depressions 41e. A concave surface 43d is formed on the bottom surface of the leg portion 43a, and a ridge 43f for supporting the peripheral portion of the intraocular lens 50 is formed on the concave surface 43d.

When the intraocular lens 50 is to be moved from the first or standby position shown in FIG. 10A to the second or insertion position shown in FIG. 10B, the head portion 43a of the push member 43 of the lens top 41 is pressed down such that the intraocular lens 50—which is nipped by the lens case base 42 and the lens case top 41 of the lens case 40 is moved to a lens movement portion 39 of the attachment portion 35. The lens movement portion 39 has a shape of a concavely-curved groove. Thus, the peripheral portion of the intraocular lens 50 comes into engagement with the reverse surfaces of the opening projection edges 39b provided at the opening of a curved concave portion 39a. As a result of this movement, the vertical position of the center of the lens 50 substantially coincides with the center axis of the push rod 33. When the push rod 33 is advanced, the intraocular lens 50 is moved within the space 15 of the lens movement portion 39 in the direction perpendicular to the page of FIG. 10B, passed through the insertion tube 32 provided integrally with the attachment portion 35, and then pushed into the eye. Since upon pressing of the push member 43 the protrusions 43c come into engagement with the depressions 41e, the intraocular lens 50 having been moved to the lens movement

portion 39 is prevented from reassuming its original shape, and reliable positioning is effected.

The lens case 40 is preferably transparent or semi-transparent, which allows an operator to check whether the lens 50 has been moved to the lens movement portion 39.

Further, it becomes possible to check whether the space 15 for allowing movement of the intraocular lens 50 is formed between the lower surface of the lens case top 41 and the lens movement portion 39 of the attachment portion 35. In other words, the push member 43 of the lens case top 41 provides two functions; i.e., the function for moving the lens 50 downward and the function for forming the lens movement space 15 in cooperation with the attachment portion 35.

As described above, the lens case 40 of the second embodiment—which consists of the lens case base 42 and the lens case top 41 including the nipping member 41a and the push member 43—provides a portion of the mechanism of the insertion device 30 upon attachment thereto.

Further, the present embodiment is characterized in that a portion of deforming means for deforming the intraocular lens 50 to a reduced size is formed integrally with the lens case 40.

That is, when the lens is moved to the lens movement portion 39 of the attachment portion 35, the lens is deformed to a reduced size. This size reduction is achieved by three design features; i.e., the lens movement portion 39 being

FIG. 12 shows cross sections corresponding to those of FIGS. 10A and 10B and showing another modification of the second embodiment shown in FIGS. 7A and 7B, in which the lens case has a modified base portion.

A lens case base 72 of a lens case 70 according to the present modification has an opening 72a on the top surface, and also has an engagement groove 72c in one of opposite side walls 72b. The engagement groove 72c penetrates the corresponding side wall 72b in a direction perpendicular to the lens insertion direction, and the attachment portion 35 is inserted into the lens case base 72 through the engagement groove 72c. When the lens case base 72 is attached to the attachment portion 35, the relative positioning between the lens case base 72 and the attachment portion 35 is effected by means of a projecting edge 72d formed at the engagement groove 72c and one of the inner surfaces of the side walls 72b.

Further, persons having skill in the art find that the lens case 70 may be easily attached to the insertion device 30 by a different method in which an operator places the lens case 70 on a table, holds in his hand the insertion device 30, and fits the attachment portion 35 into the lens case 70 through the engagement groove 72c.

During use of the insertion system, an operator wears gloves, which hinders fine operation. Therefore, attachment of the lens case 70 is preferably performed in a method in which an operator places the lens case 70 on a support, holds

in his hand the insertion device 30, which is larger and easier to hold than the lens case 70, and fits it onto the lens case 70 from one side thereof.

The remaining structure is the same as that of the above-described second embodiment. When the intraocular lens 50 is to be inserted into the eye, the push member 73 of the lens case top 71 is depressed to thereby move the intraocular lens 50 into the lens movement portion 39 of the attachment portion 35, and the intraocular lens 50 is then inserted into the eye from the tip end of the insertion tube through advancement of the push rod 33.

FIG. 13 is a plan view showing a modified example of the insertion tube 32 of the insertion device 30 used in the second embodiment.

In this modification, the insertion tube 32 is formed integrally with the attachment portion 35 of the insertion device 30, such that a groove-shaped curved depression 39a serving as a lens deforming means is formed on the base end side of the insertion tube 32.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the present invention may be practiced otherwise than as specifically described herein.